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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Proposed Regulations on Registration of Food Facilities Under Public Health Security and Bioterrorism Preparedness and Response Act of 2002, **Docket No. 02N-0276**

The American Chemistry Council (ACC) Biocides Panel (Panel) is submitting these comments on behalf of its 46 member companies. A list of the Panel's members is attached. Panel members are engaged in the manufacture, formulation, distribution and sale of antimicrobial active ingredients and formulated end use products registered and regulated by EPA as pesticides pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Some of these EPA-registered antimicrobial pesticides also are regulated by FDA as food additives pursuant to FFDCA section 409 and others are also regulated by EPA as pesticide chemical residues pursuant to FFDCA section 408. The Panel appreciates this opportunity to comment and urges FDA to incorporate the following information into its continuing deliberations. For the reasons discussed below, the Panel requests that FDA clarify that antimicrobial pesticides are *not* included within the definition of "food" for purposes of this proposed regulation.

The regulation proposed to be codified at 21 CFR 1.227 defines "food" as the term is defined in FFDCA section 201(f). The regulation also provides an extensive list of examples of what constitutes food for purposes of this rule. The list includes "additives, including substances that migrate into food from food packaging and other articles that contact food." The inclusion of the term "additives" has the effect of extending the definition of food to "substances, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food." 21 CFR § 170.3(e)(1). As a consequence, the proposed regulation, as currently written, applies to any antimicrobial pesticide that ultimately may contact or be incorporated into an article that contacts food by "indirect" or "secondary direct" means, consistent with existing, explicit FDA and/or EPA approval.

These substances are not food *per se and* are not intended to become part of food under approved conditions for use. Nonetheless, because some migration to food from their use may occur, FDA regulates such food contact uses of such substances pursuant to FFDCA section 409 and 21 CFR parts 173 through 178. There are numerous FDA approved food additive uses of antimicrobial pesticides. For example, antimicrobials used in fruit and vegetable rinses in food processing facilities and in beet and

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1300 Wilson Boulevard, Arlington, VA 22209 ▪ Tel 703-741-5600 ▪ Fax 703-741-6091 ▪ http://www.americanchemistry.com

cane sugar mills to control pathogenic and spoilage microorganisms are regulated as secondary direct food additives. Antimicrobial slimicides used to control microorganisms in pulp and paper mills as an integral function of the manufacture of paper are regulated as indirect food additives. Likewise, antimicrobial material preservatives are used in articles that may come in contact with food; for example, adhesives in food packaging, paper and packaging coatings, and various polymers (e.g., those used in conveyer belts in food processing facilities, restaurant equipment, dairy and milking equipment) are regulated as indirect food additives. Antimicrobial preservatives are used in these and numerous other manufactured goods and articles, including those that may contact food, to protect the articles from deterioration. Preservation is necessary to extend the useful life of such goods, resulting in significant consumer benefits, economic savings and resource conservation.

EPA regulates antimicrobials intended for use on food-contact hard surfaces and aseptic packaging as pesticide chemical residues. These antimicrobials are not applied to food. Instead they are used to control pathogenic microorganisms on hard surfaces that contact foods. Prior to 1996 they were regulated by FDA as indirect food additives. They continue to meet the definition of food additive, in that their presence in food would occur only by migration from a treated surface to food. Therefore, it is possible that antimicrobials registered for these uses also could be subject to the regulation.

The Panel does not believe that antimicrobial pesticides with FDA and/or EPA approvals for uses that could be reasonably expected to migrate to food should be considered "food" within the context of this regulation. To do so would require chemical manufacturing, storage and distribution facilities handling antimicrobial active ingredients and formulated products to register as food facilities, when, in fact, they are not. Ironically, other chemical manufacturing, storage and distribution facilities that handle pesticide products applied *directly* to food as it is grown or stored would *not* be required to register as food facilities because these uses do not fall within the definition of food additives. This incongruous result, the Panel believes, certainly is unintended.

Moreover, most antimicrobial active ingredients and formulated products have numerous non-food uses, frequently far more than food uses. As a consequence, FDA would be collecting facility information on only a subset of pesticide manufacturers, with varying and in many instances minimal amounts of their registered pesticides ultimately being used in ways that may contact food. It is difficult to see how such information collection could serve any useful purpose.

Finally, the food facility registration requirement, when applied to antimicrobial pesticide manufacturing, storage and distribution, duplicates the EPA requirement that every facility where any pesticide is produced must be registered as a "pesticide producing establishment." 40 CFR Part 167. "Produce" is broadly defined and includes "to manufacture, prepare, propagate, compound, or process any pesticide . . . or to package, repackage, label, relabel, or otherwise change the container of any pesticide." 40 CFR § 167.3. Each registered pesticide establishment is required to submit an annual pesticide production report. 40 CFR § 167.85. The unique, EPA-assigned establishment registration number of the last registered pesticide producing establishment at which any "production" occurs, must be displayed on the EPA-approved label for the pesticide product. 40 CFR § 156.10(f). EPA's requirements are more than adequate to address any needs that FDA might have in identifying the facility at which an antimicrobial pesticide was produced, relabeled, repacked, etc.

In conclusion, the Panel requests that FDA clarify that this regulation requiring food facility registration is not applicable to facilities engaged in antimicrobial pesticide activities. Such a requirement force FDA to collect and review prior notices but would not provide FDA with meaningful or useful information. Moreover, EPA already collects this information in a far more comprehensive manner, so

information. Moreover, EPA already collects this information in a far more comprehensive manner, so that such a regulation would impose a duplicative paperwork burden on the antimicrobial pesticide industry but without any corresponding benefit.

If you have any questions regarding these comments or related issues, please do not hesitate to Dr. Hasmukh C. Shah of my staff at 703-741-5637.

Attachment

Sincerely yours,

Courtney M. Price
Vice President, CHEMSTAR

cc: Stuart Shapiro (OMB)

American Chemistry Council
Biocides Panel Member Companies

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AEGIS Environments
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Albemarle Corporation
Alcide Corporation
Ameribrom, Inc.
Arch Chemicals, Inc.
Ashland Chemical
Avecia Inc.
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